

Application No. 10/609,346
Response Dated November 21, 2006
Reply to Office Action of August 24, 2006

REMARKS/ARGUMENTS

1. Remarks on the Amendment

The Specification has been amended to correct typographic and clerical errors.

Claims 21-23, 27-33, 40 and 41 have been cancelled without prejudice.

New Claims 51-67 have been added to more specifically define Applicant's claimed invention.

Antecedent basis of the amendment of independent Claim 51 can be found on page 37, lines 20-31, and page 39, lines 5-11 and of the Specification and claims as filed.

Applicants submit that no new matter has been introduced by the amendment.

2. Response to the Rejection of Claims 21-23, 27-33, 40-41 under 35 U.S.C. §112, first paragraph (Items 2a and 2b of the Office Action)

Claims 21-23, 27-33, and 40-41 stand rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement and the enablement requirement. These rejections are respectfully traversed by the amendment.

Claims 21-23, 27-33, and 40-41 have been canceled. However, the rejections have been fully addressed in the new Claims 51-67. Applicants submit that new Claims 51-67 meet the written description and the enablement requirement of 35 USC §112, first paragraph.

Accordingly, Applicants respectfully request withdrawal of the rejection of based upon 35 U.S.C. §112, first paragraph.

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3. Response to the Rejection of Claims 21-23, 27-31, 33, 40-41 under under 35
U.S.C. §112, second paragraph

Claims 21-23, 27-33, and 40-41 stand rejected under 35 USC §112, second paragraph. This rejection is respectfully traversed by the amendment.

Claims 21-23, 27-33, and 40-41 have been canceled. New Claims 51-67

~~have particularly pointing out and distinctly claimed the subject matter which the~~
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Applicant submits that nothing in the art of record teaches or suggests the subject matter positively recited in the Claim 51. As recited in Claim 51, Applicants' claimed comprising a member selected from the group consisting of (a) a polynucleotide encoding a polypeptide as set forth in SEQ ID NO. 8; and (b) a polynucleotide contained in ATCC Deposit No: PTA-4607.

Shaw teaches site-specific homogeneous modification of polypeptides by attachment of compounds having amine reactive groups. Shaw merely teaches G-CSF is suitable for such a modification.

As pointed out by the Examiner, Shaw fails to teach a polynucleotide encoding both G-CSF and albumin to obtain a fusion protein comprising G-CSF and albumin to increase the half-life of G-CSF.

Shaw's deficiencies are not overcome by Capon et al.

Capon et al. teach nucleic acid encoding a polypeptide fusion comprising a ligand binding partner protein fused to a stable plasma protein. The ligand binding partner are proteins known to function to bind specifically to target ligand molecules, and are generally found in their native state as secreted or membrane bound polypeptides. Capon et al. teach that the stable plasma protein extends the in vivo plasma half-life of the ligand binding partner when present as a fusion with the ligand binding partner.

Furthermore, Capon et al. specifically teach that a large number of proteins having various structures, sources, and biological functions are not suitable, therefore, excluded from the ligand binding partner of their invention.

Capon et al. fail to teach Applicants' claimed polynucleotide encoding a polypeptide as set forth in SEQ ID NO. 8, or a polynucleotide contained in ATCC Deposit No: PTA-4607, which encodes albumin and G-CSF to obtain a HSA/G-CSF

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albumin, to obtain a chimeric protein with an increased circulating half-life.

Applicants respectfully disagree.

First, *In re Dow Chem.*, 837 F.2d 469, 473, 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988), the case law has clearly stated that "the consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art." Therefore, the first requirement is that a showing of a suggestion, teaching or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352, 48 USPQ 2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." *In re Dembiczak*, 175, F.3d 994, 1000, 50 USPQ 2d 1614, 1617.

The second requirement is that the ultimate determination of obviousness must be based on a reasonable expectation of success. *In re O'Farrell*, 853 F.2d 894, 903-904, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988); see also *In re Longi*, 759 F.2d 887, 897, 225 USPQ 645, 651-52 (Fed. Cir. 1985). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the

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fusion protein retains the structure of the original proteins which are responsible for
the biological functions and its actual bio-activity.

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